

### **REMARKS / ARGUMENTS**

#### **1. Dayco / McKesson Disclosure**

In accordance the undersigned's current understanding of the obligations imposed by *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) and *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), the following co-pending application(s) whose file history may contain material information are identified. In assessing the patentability of the pending claims, the Office is respectfully requested to review the file history of each the listed co-pending application(s), determine whether such co-pending application has "similar subject matter" and, if so, consider each Office Action, including each reference on which a rejection is based, and each paper submitted by applicant therein.

a. The subject matter of this application may be related to the subject matter of application serial no. 10/501,112, which is currently pending before Examiner Evanisco. This application is currently on Appeal.

b. The subject matter of this application may be related to the subject matter of application serial no. 11/663,115, which is currently pending before Examiner Bockelman, has not yet been examined.

c. The subject matter of this application may be related to the subject matter of application serial no. 12/134,084, which is currently pending before Examiner Getzow. A non-final rejection was mailed on October 5, 2010 rejecting all of the claims on the ground of non-statutory double patenting.

#### **2. Response to 08/19/2010 Non-Final Office Action**

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in *9-point bolded and italicized font*. Assignee's arguments immediately follow in regular font.

*Claims 20-31 are rejected under 35 U.S.C. 101 because the claimed method is not tied to a particular structure. The steps of performing a time/frequency analysis must be tied to a specific structure or machine.*

As previously argued, the Board of Patent Appeals and Interferences recently held that “a computerized method which includes a step of outputting information from a computer [is] tied to a particular machine or apparatus”. *Ex Parte Dickerson*, Appeal 2009-001172 (BPAI 2009). In the present case, claim 20 recites “outputting, from the controller, a control signal...”. Thus, the Board has already ruled on this issue and agrees with Assignee that the claims are “tied to a particular machine or apparatus”. The recent United States Supreme Court ruling in *Bilski* merely held that this “machine or transformation” test is not the only test. Of course, in the present case, the claims meet this test, and are therefore, directed to patent eligible subject matter. For at least these reasons, Assignee respectfully submits that claim 20 was directed to statutory patentable subject matter. However, in an effort to advance prosecution, claim 20 has been amended.

Claim 20 now recites “receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform; analyzing, in the controller, the flow waveform in the time domain; analyzing, in the controller, the flow waveform in the frequency domain; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform in the time domain and analysis of the flow waveform in the frequency domain”. Thus, each and every step is now tied to the controller, a specific machine, and thus meets the ‘machine or transformation’ test.

***Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification appears to be silent regarding the method step of analyzing the flow waveform in both the time domain and frequency domain.***

***The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).***

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The specification has been amended to now explicitly include description that was previously incorporated by reference. Because this ground of rejection was not mentioned in the Advisory action, Assignee believes these amendments to be sufficient.

***Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,396,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to obvious variations of controlling a blood pump by analyzing a flow waveform or signal in both a time domain and a frequency domain.***

Assignee does not accede that the claims are not patentably distinct. However, in an effort to advance prosecution, Assignee stands ready to file a terminal disclaimer, should no other grounds of rejection be sustained for Appeal.

***Claims 20, 22, 26-29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US 4989609).***

***As to claim 20, Smith discloses a method of controlling a blood pump, comprising: receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform; analyzing the flow waveform in both the time domain and frequency domain; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform (Figs. 3, 7; col. 8 ll. 1-35).***

As an initial matter, Assignee does not accede to the Office's characterization of Smith as applied to the claims and Assignee respectfully reserves its right to present additional challenges that characterization in the future.

"A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631 (Fed. Cir. 1987). As the Court of Appeals for the Federal Circuit has held, "The test for anticipation is whether the claim reads on the product or process disclosed in the prior art, ***not on what that reference broadly teaches.***" *SSIH Equip. S.A. v.*

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*United States Int'l Traded Comm'n*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983) (emphasis added). Further, the law of anticipation requires that the prior art reference disclose each claim limitation **arranged as in the claim**. See, e.g., *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001) (“to anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim”); *Karsten Mfg. Corp. v. Cleveland Golf* 242 F.3d 1376, 1383 (Fed. Cir. 2001); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 47 USPQ2d 1225 (Fed. Cir. 1998) (“a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device.”); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990) (“These elements must be arranged as in the claim under review.”). The Office may not establish anticipation by mere “substantial similarity” between the prior art disclosure and the arrangement of claim limitations. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985). Rather, the Office may reject a claim as anticipated **only** when each and every claim limitation must be described identically in the single prior art reference. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Claim 20 now recites “receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform; **analyzing, in the controller, the flow waveform in the time domain; analyzing, in the controller, the flow waveform in the frequency domain**; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform in the time domain and analysis of the flow waveform in the frequency domain”, emphasis added.

In contrast, as previously argued, Smith appears to be completely devoid of any implanted flow sensor and/or blood pump, and therefore cannot receive “a flow signal from **an implanted flow sensor**,” as claimed, or output “a control signal to control **an implanted blood**

**pump**", as claimed. In fact, it appears, as best understood, that Smith's source 10, tubing 20, and demodulator 34, along with other associated components, are all **external** to any body. Assignee has certainly found no explicit teaching of them being implanted, as required by the claim. Furthermore, Smith merely appears to teach determining an accurate flow rate, rather than performing any sort of pump **control**. Therefore, Smith appears to be devoid of outputting any **control** signal.

Finally, rather than "analyzing, in the controller, the flow waveform **in the time domain**", as required by the claim, Smith explicitly admits that his "Doppler blood flow system calculates flow rate solely on the basis of frequency". Abstract. See *also* column 3, lines 10-12 ("the flowmeter of the present invention and the method invoked therein calculates flow rate solely on the basis of frequency").

Assignee acknowledges that Smith teaches converting a time domain signal to the frequency domain. For example, Smith discusses an article by Murphy and Rolfe, in the background section saying that "Murphy et al uses Fast Fourier Transform (FFT) techniques to convert from the time domain to the frequency domain and to digitally obtain the average frequency which corresponds to the blood flow measured." Then, in column 8, lines 13-16, Smith explains how his "waveform is then converted 316 into the frequency domain by Fast Fourier Transform (FFT) to calculate the frequency distribution of the signal." Therefore, Smith does convert from the time domain to the frequency domain. However, this **conversion** is not **analysis**, certainly not as disclosed and claimed in the present application. Thus, Smith never performs any **analysis** based in the time domain, much less outputting a control signal in response to both the analysis of the flow waveform in the time domain and analysis of the flow waveform in the frequency domain, as claimed.

Of course, regardless of the distinction between **converting** from the time domain and

actually performing **analysis** of the time domain signal, Smith fails to teach “receiving ... a flow signal from an **implanted** flow sensor” and “outputting ... a **control** signal to control an implanted blood pump”, as discussed above. Therefore, it appears that Smith is completely devoid of several of the claimed method steps. At the very least, Smith does not disclose each of the claim limitations, **arranged as in the claim**. For at least these reasons, Assignee respectfully submits that claim 20 is patentable over the disclosure and teaching of Smith. Reconsideration and withdrawal of this rejection is requested.

### 3. Conclusion

In responding to this Office Action, Assignee has presented only those arguments and made only those amendments that Assignee believes are warranted. Assignee has not, for example, responded to every factual or legal issue raised by the Office, and Assignee has not presented every argument supporting patentability that may be relevant. The decision not to address a factual or legal issue raised or to present a certain argument in support shall not be construed as Assignee's agreement with the Office on such issue or effect a waiver of Assignee's right to address such issues or make such arguments in the future.

Claims 20-31 are currently pending in this application. Assignee submits that each claim presented herein is patentable. A timely notice of allowance is respectfully requested.

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Assignee thanks the Examiner for his/her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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